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	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	10/560,657	12/13/2005	Carl-Johan Aureli	101078 - 1P US	2259
	52286 COZEN O'CON	T STREET	•	EXAMINER	
	1900 MARKET PHILADELPH			VALENROD, YEVGENY	
				ART UNIT .	PAPER NUMBER
				1621	
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l	SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE PAPER	
Ī	3 MO	NTHS	02/15/2007		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
Office Action Summary	10/560,657	AURELL ET AL.				
Office Action Gammary	Examiner	Art Unit				
The MAII INC DATE of this communication and	Yevgeny Valenrod	1621				
The MAILING DATE of this communication app Period for Reply	ears on the cover sneet with the c	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on	1) Responsive to communication(s) filed on					
2a) This action is <b>FINAL</b> . 2b) This						
3) Since this application is in condition for allowar	,—					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.				
Disposition of Claims	•					
4)⊠ Claim(s) <u>1-7</u> is/are pending in the application.	Claim(s) <u>1-7</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-7</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) acce	epted or b) objected to by the	Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct		, ,				
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119		·				
12)⊠ Acknowledgment is made of a claim for foreign a)⊠ All b)□ Some * c)□ None of:	priority under 35 U.S.C. § 119(a	)-(d) or (f).				
<ol> <li>Certified copies of the priority documents</li> </ol>	s have been received.					
2. Certified copies of the priority documents	• •					
3. Copies of the certified copies of the prior	·	ed in this National Stage				
application from the International Bureau	• • • • • • • • • • • • • • • • • • • •					
* See the attached detailed Office action for a list	of the certified copies not receive	ed.				
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>	4) Interview Summary Paper No(s)/Mail D					

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/13/05.

5) Notice of Informal Patent Application
6) Other:

Application/Control Number: 10/560,657

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindstedt et al. (US 2005/0171204).

Instant claims are directed to amine salts of (2S)-2-ethoxy-3-(4-{2-[hexyl(2-phenylethyl)-amino]-2-oxoethoxy}phenyl)propanoic acid (from now on Compound I). Specific amine salts are claimed in claims1-4. Claim 5 is directed to a salt which is a hydrate, solvate or mixed. Claims 6 and 7 are directed to crystalline or partially crystalline forms of the salt.

## Scope of prior art

Lindstedt et al. teach the free acid of compound 1 (page 2, paragraph [0021]).

They also teach ammounium and basic amino acid salts of the free acid acid

(paragraph [0023], line4) and crystalline forms (paragraph [0022]). In paragraph [0024],

lines 1-3, Lindstedt et al. teach the hydrated form of the compound.

Ascertaining the difference between prior art and the instant claims

Lindstedt et al. teach ammonium salts of the free acid of compound I. However they do not teach the specific ammonium salts found in claim 1.

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## Obviousness

Ammonium salts of pharmacologically active compounds are common in the art. Lindstedt et al. broadly teach salts of the compound of formula I and specifically mention ammonium salts. The instant invention claims particular ammonium salts. The claimed salts are not patentable over Lindsdedt et al. absent unexpected results arising from the use of specific ammonium counterions listed in the claims. In the specification, on page 2, applicant compares the compounds of the instant invention to those found in PCT/GB02/05743. The alleged unexpected result of the ammonium salts claimed by the applicant, is that it can be made into a crystalline form. Examiner would like to note that the compounds of PCT/GB02/05743 are structurally different from those of the instant invention. Therefore, the alleged unexpected result is not applicable to the instant case. In order to claim unexpected result the applicant needs to supply evidence that would make clear what advantage the ammonium salts of compound I claimed by the applicant have over the salts described by Lindstedt et al.

#### Conclusion

Claims 1-7 are pending

Claims 1-7 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yevgeny Valenrod

**Patent Examiner** 

Technology Center 1600

Supervisory Patent Examiner

Technology Center 1600